

**Remarks**

Reconsideration and allowance of this application, as amended, are respectfully requested.

The written description portion of the specification, claims 1 and 3-18, and the abstract of the disclosure have been amended. Claim 2 has been canceled without prejudice or disclaimer. New claims 20 and 21 have been added. Claims 1 and 3-21 are now pending in the application. Claims 1 and 20 are independent. The rejections are respectfully submitted to be obviated in view of the amendments and remarks presented herein. No new matter has been introduced through the foregoing amendments.

The specification has been editorially amended for conformance with 37 CFR § 1.77(c), for consistency, and to correct any informalities. The abstract has been editorially amended for conformance with 37 CFR § 1.72(b). The claims have been amended to overcome each ground of rejection, and in general to more fully comply with U.S. practice. In view of the aforementioned claim amendments for compliance, new dependent claim 19 has been added to define a feature of the invention previously presented in original claim 14.

Claim 1 has been amended to incorporate a feature of the invention previously presented in now-canceled claim 2. Instant claim 1 defines an embodiment of the invention that includes, *inter alia*, "more than two porous elements being arranged in the filter

device such that any of said porous elements has a higher hydrophilicity than a successive porous element in a direction of flow, from said inlet to said outlet, of said blood product through said filter device." See, e.g., Applicants' disclosure at specification page 5, third full paragraph.

New claims 20 and 21 have been added to further define the scope of protection sought for Applicants' invention.

Entry of each of the amendments is respectfully requested.

35 U.S.C. § 102(b) - Bormann

Claims 1-3, 7-13, and 16-18 stand rejected under 35 U.S.C. § 102(b) as being anticipated by WO 00/54873 of Bormann et al. (hereinafter "Bormann"). The examiner asserts in pertinent part that Bormann teaches that "the first porous element has a higher hydrophilicity than the successive filter element in the direction of flow, from inlet to outlet in the direction of blood flow (Page 12, lines 6-9, Figs. 1-3)" (Office Action page 3).

The rejection of claims 1-3, 7-13, and 16-18 under § 102(b) based on Bormann is respectfully deemed to be obviated. For at least the following reasons, the disclosure of Bormann does not anticipate Applicants' presently claimed invention.

Bormann's filter is structurally and functionally different from Applicants' presently claimed filter device. With regard to the above-quoted excerpt from the Office Action,

Applicants respectfully submit that in paraphrasing original claim 1 of the instant application, the examiner unfairly characterizes the disclosure of Bormann. In the portion of Bormann's disclosure relied upon in the Office Action (i.e., page 12, lines 6-9), Bormann actually discloses the following:

Typically, the first element 1 and the second element 2 each have a CWST of at least about 55 dynes/cm, more typically, at least 58 dynes/cm. Preferably, the first element 1 and the second element 2 each have a CWST of at least about 62 dynes/cm. The CWST of one element (e.g., the first element) can be different than the CWST of another element (e.g., the second element). Illustratively, one of the elements can have a CWST in the range of from about 58 dynes/cm to about 75 dynes/cm, and another element can have a CWST in the range of from about 78 dynes/cm to about 115 dynes/cm.

In fact, in referring to a first element and a second element, Bormann simply fails to unambiguously disclose a device in which the first element has a higher hydrophilicity than the second element, let alone that "any of said porous elements has a higher hydrophilicity than a successive porous element in a direction of flow," per Applicants' present claim 1.

Furthermore, if Bormann's reference to "one of the elements" is interpreted to be a reference to his first element and the reference to the "another element" is interpreted to be a reference to his second element, then it appears as though the quoted passage describes a filter with an *increasing* hydrophilicity from inlet to outlet (i.e., first a CWST in the range of from about 58 dynes/cm to about 75 dynes/cm, and then a CWST in the range of

from about 78 dynes/cm to about 115 dynes/cm). And, still further, the disclosure relied upon by the examiner only refers to a filter having two filter elements.

That, however, is not Applicants' presently claimed invention. As indicated above in the introductory remarks, instant claim 1 defines an embodiment of the invention that includes "*more than two porous elements being arranged in the filter device such that any of said porous elements has a higher hydrophilicity than a successive porous element in a direction of flow, from said inlet to said outlet, of said blood product through said filter device.*"

Consequently, the claimed filter device has a decreasing hydrophilicity profile (i.e., a negative gradient) in the direction of flow from inlet to outlet. The instant specification provides evidence that the decreasing hydrophilicity profile is beneficial in that it leads to an improved leukocyte removal efficiency and to further advantages, such as reduced priming pressure and priming time of the filter (see, e.g., specification pages 8 and 9).

As further evidence of the distinctions relative to Bormann, Applicants note the following. In Bormann's Example 1, there are eleven alternating filter elements. The odd-numbered filter elements have a CWST of 95 dynes/cm, which is higher than the CWST of the even-numbered filter elements. The same situation applies to Bormann's Example 4. Therefore, in a filter configuration in which there are more than two filter elements,

Bormann clearly discloses an *alternating* hydrophilicity profile from inlet to outlet. Clearly, Bormann does not teach a filter having a negative hydrophilicity profile, let alone Applicants' claimed filter device and all of the advantages associated therewith.

Since Bormann does not meet each feature of the claimed invention, Bormann does not anticipate the invention defined by Applicants' instant claim 1. Claims 3, 7-13, and 16-18 are allowable because they depend, either directly or indirectly, from claim 1, and for the subject matter recited therein.

35 U.S.C. § 103(a)

Since Bormann is the primary reference in each of the rejections under § 103(a) -- claims 4 and 5 as being unpatentable over Bormann in view of U.S. Patent No. 4,925,572 to Pall; claim 6 as being unpatentable over Bormann in view of U.S. Patent No. 5,298,165 to Oka et al. ("Oka"); and claims 14 and 15 as being unpatentable over Bormann in view of U.S. Patent No. 5,190,657 to Heagle et al. ("Heagle") -- each of these rejections is also respectfully deemed to be obviated. The combined disclosures of the cited references would not have rendered obvious Applicants' presently claimed invention because the disclosures of the additional references do not rectify any of the above-described deficiencies of Bormann.

Furthermore, there is simply no teaching in any of the references that would have led one to select the references and combine them in a way that would produce the invention defined by any of Applicants' presently pending claims.

Therefore, the various combinations of references would not have rendered obvious the invention defined by any of Applicants' presently pending claims.

New claims 20 and 21 have been added to further define the scope of protection sought for Applicants' invention. New claims 20 and 21 are also allowable. Claim 20 defines an embodiment of the invention that includes, *inter alia*, "more than two porous elements disposed within said housing, each of said porous elements (i) being configured to remove leukocytes, (ii) having at least two adjacent layers of a filtering material, and (iii) having a different hydrophilicity relative to one another." In addition, claim 20 recites that "said more than two porous elements [are] arranged in the filter device such that, in said flow direction, each of said porous elements has a higher hydrophilicity than a successive porous element."

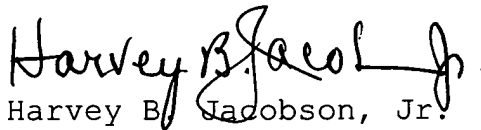
Since independent claim 20 includes at least the features discussed above with respect to the rejection over Bormann, the reference neither anticipates nor would have rendered obvious the embodiment of the filter device defined by claims 20 and 21.

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In view of the foregoing, this application is now in condition for allowance. If the examiner believes that an interview might expedite prosecution, the examiner is invited to contact the undersigned.

Respectfully submitted,

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